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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/512,024	05/09/2005	Abdullah Ibrahim Haj-Yehia	YISS2000100	2208

7590 06/13/2007
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EXAMINER

FREISTEIN, ANDREW B

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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06/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/512,024

Applicant(s)

HAJ-YEHIA, ABDULLAH IBRAHIM

Examiner

Andrew B. Freistein

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-28 is/are pending in the application.
- 4a) Of the above claim(s) 12-22 and 26-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,23 and 25 is/are rejected.
- 7) ☒ Claim(s) 2-9 and 23-25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>20070608</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>04/07/2005</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

The amendment filed 04/30/2007 was entered. Claims 1-9 and 12-28 are pending. Claims 10 and 11 were cancelled.

Priority

This application is a 371 of PCT/IL03/00312, filed 04/15/2003, which claims benefit of US Provisional Application No. 60/374,173.

Information Disclosure Statement

Applicant's information disclosure statement (IDS), filed on 04/07/2005, has been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Restriction Requirement

In a response filed 04/30/2007, Applicant elected (with traverse) Group I, claims 1-9 and 23-25. Applicant traverses the restriction requirement asserting that unity of invention is not lacking, because the definition of R³ and R⁴ of the compound claims were amended. However, as a result of the indefiniteness of this amendment (see 35 U.S.C. 112 rejection below), the amendment does not necessitate the withdrawal of the restriction requirement. Furthermore, the Examiner respectfully disagrees with the Applicant because Inventions I-VI differ materially in structure and element and from each other and are therefore capable of supporting their own patents. Groups I-VI are related to a set of structurally diverse compounds, their methods of use, and pharmaceutical compositions with intended use, inhalation devices and kits.

Nevertheless, Examiner may reconsider to rejoin the method of use claims and the pharmaceutical composition claims commensurate in scope with the product claims

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when and if the case is found to be in condition for allowance provided those method of use claims and pharmaceutical composition claims are free of 35 U.S.C. § 112 first and second paragraph issues (including written description, reach-through claim language and/or scope of enablement issues).

Applicants reserve their right to file a divisional application on the non-elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(1) Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, on page 5, the claim limitation states, "wherein at least one of R¹, R², R³ and R⁴ **comprises** at least one ROS scavenger..." Similarly, in the next paragraph, claim 1 states, "wherein one or more R¹, R², R³ and R⁴ **comprise** at least one NO donor..."

Claim 3 is drawn to a β -agonist compound...wherein the saturated heterocycle "**comprises**" a substituted nitroxide.

Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites

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members as being “selected from the group consisting of A, B and C.” See *Ex parte Markush*, 1925 C.D. 126 (Comm’r Pat. 1925).

The terms “**comprise**” and “**comprises**” are inclusive or open-ended transition phrases that do not exclude additional, unrecited elements or method steps. In *Gillette Co. v. Energizer Holdings Inc.*, 405 F.3d 1367, 1371-73, 74 USPQ2d 1586, 1589-91 (Fed. Cir. 2005), the court held that a claim to “a safety razor blade unit comprising a guard, a cap, and a group of first, second, and third blades” encompasses razors with more than three blades because the transitional phrase “comprising” in the preamble and the phrase “group of” are presumptively open-ended. “The word comprising’ transitioning from the preamble to the body signals that the entire claim is presumptively open-ended.” *Id.* In contrast, the court noted the phrase “group consisting of” is a closed term, which is often used in claim drafting to signal a “Markush group” that is by its nature closed. *Id.*

Moreover, R³ and R⁴ are previously defined to “together form a 5 to 7-membered saturated heterocycle having 1 or 2 heteroatoms independently selected from nitrogen, and oxygen, and sulfur.” R³ and R⁴ cannot comprise an ROS scavenger or an NO donor group unless those groups are specifically defined in terms of 5 to 7-membered saturated heterocyclic groups having 1 or 2 heteroatoms selected from N, O or S atoms.

In order to overcome this rejection, the following limitations should be deleted:

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wherein at least one of R^1 , R^2 , R^3 and R^4 comprises at least one ROS scavenger selected from the group of moieties consisting of a nitroxide free radical, alkenyl, sulfhydryl or dithiol in oxidized or reduced form, and aryl; and

wherein one or more of R^1 , R^2 , R^3 and R^4 comprise at least one NO donor selected from $—ONO$, $—ONO_2$, and $—SNO$.

(2) Claim 23 recites the limitation "or a solvate thereof or an optical isomer thereof." There is insufficient antecedent basis for this limitation in the claim, because claim 1 is only drawn to the compound and salt.

(2) Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 lists fifteen additional active agents that can be part of the pharmaceutical composition. However, except for the β -agonist, none of the other agents are exemplified in the specification. In order to overcome this rejection, claim 25 should be amended to cancel the other 14 agents or cancelled.

Claim Objections

Claim 9 is objected to, because there is no period at the end of the claim.

Claims 2-9 and 23-25 are objected to as being dependent upon a rejected base claim.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^{rs}Kane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).



REBECCA ANDERSON
PATENT EXAMINER

Andrew B. Freistein
Patent Examiner, AU 1626

for Joseph K. M^{rs}Kane
Supervisory Patent Examiner, AU 1626
Date: June 8, 2007